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Michael J. Urbano 1445 Princeton Drive Bethlehem, PA 18017-9166		PELLEGRINO, BRIAN E			
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/798,064

Filing Date: March 11, 2004

Appellant(s): ARNEY ET AL.

Michael Urbano
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/14/10 appealing from the Office action mailed 11/19/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:
Claims 1-21 are pending and rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

4,718,907	Karwoski et al.	1-1988
WO 02/064019	Bailey et al.	8-2002
2004/0115239	Shastri et al.	6-2004
2005/0027350	Momma et al.	2-2005
2003/0040791	Oktay	2-2003
2005/0079200	Rathenow et al.	4-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8,12,13,18-20 are rejected under 35 U.S.C. 103(a) as obvious over Bailey et al. (WO 02/64019) in view of Karwoski et al. (4718907). Bailey et al. disclose the stent is made of metal material (page 16). Metal is known to possess some amount of hydrophobicity. Bailey further discloses the stent can also include an array of microstructures or grooves and hydrophobicity can be controlled in dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects hydrophobicity. However, Bailey does not explicitly state the hydrophobicity of the surface is established with a contact angle greater than 90° when a body fluid drop contacts it. Karwoski et al. teach to coat inner surfaces of prostheses with a coating that provides a hydrophobicity that a drop of body fluid will have a contact angle greater than 90° to give it a non-thrombogenic surface, col. 2, lines 61-68, col. 3, lines 1-3,13-18,58-61. It would have been obvious to one of ordinary skill in the art to coat the inner surface of the device of Bailey with the coating of Karwoski et al. to provide a hydrophobic surface to give a contact angle to fluid greater than 90° since such that it reduces thrombogenicity. Regarding claims 2,7 Bailey discloses a control device, page 5, lines 3-5. With respect to claim 3, Bailey additionally discloses the control device includes electronic components, page 5, lines 3-11. Regarding claim 4, Bailey states it can be controlled remotely from an external source, page 15, lines 11,12,17-19. With respect to claim 5, there is chemically active substances adhered to the stent, page 23,

lines 5-10. Regarding claim 8, Bailey also discloses that forms of electrical energy are applied to the control device which is capable of applying a voltage between the array and substrate, page 15, lines 17-19, page 23, lines 5-31. Bailey additionally discloses controlled release of substances by electrical energy, page 23, lines 23-31. With respect to claims 12,13, Bailey discloses means for altering the shape and the diameter, page 16, lines 1-32, 23 lines 24-28. Regarding claim 19, please note that “isolated zones” is an arbitrary limitation and an elongate element, such as a stent can be said to have two arbitrary ends with arbitrary zones present as established in Figs. 1 and 3 since the means for applying electrical energy is spaced about the surface. Also the presence of grooves can be said to clearly establish isolated surface zones. Regarding claims 8, 19 it is noted that a fluid is capable of being suspended over the microstructures in a first state and then penetrates between the microstructures in a second state. It is also evident as seen in Fig. 4, that medicinal material is in the microstructures.

Claims 1,2,5-7,9-11 are rejected under 35 U.S.C. 103(a) as obvious over Momma et al. (2005/27350) in view of Karwoski et al. ‘907. Fig. 2 shows a stent body **42** that includes an array microstructures **38** and control device in the form of a membrane **46** to vary hydrophobicity. The array of microstructures include surfaces of exposed and having chemically active substances in two zones **52, 54** adhered thereto capable of release at different times. Momma et al. disclose the stent is a metal and thus has a hydrophobic surface, paragraph 35. Momma additionally discloses the chemically active substances can be different, paragraphs 21,45. However, Momma does not explicitly state the surface is hydrophobic with a contact angle greater than 90°

when any drop of fluid contacts it. Karwoski et al. is explained supra. It would have been obvious to one of ordinary skill in the art to coat an inner surface as taught by Karwoski et al. such that it has a contact angle to fluid greater than 90° on the inner side of the stent of Momma such that it is non-thrombogenic.

Claims 1,2,5-7,15-17 are rejected under 35 U.S.C. 103(a) as obvious over Shastri et al. (2004/115239) in view of Karwoski et al. '907. Shastri et al. disclose an implant having a plurality of fibers or particles of nanosize placed on its surface, paragraph 48,49. Shastri also discloses the nano-material can be silicon (paragraphs 41,52) a semiconductor material. Shastri additionally discloses the implant can be a stent, paragraph 54. The nanostructures have a size within the range of 4µm to 20nm, paragraph 69. Shastri discloses chemically active substances can be used on the device with control devices (polymer materials), paragraphs 75,79,82,84. These include cells that change the surface properties or hydrophobicity. Shastri discloses (paragraph 87) properties modified or controlled, including wettability that the Examiner interprets to affect the hydrophobicity. However, Shastri does not explicitly state the surface is hydrophobic with a contact angle greater than 90° when any drop of fluid contacts it. Karwoski et al. is explained above. It would have been obvious to one of ordinary skill in the art to coat an inner surface of the Shastri device to provide a hydrophobic surface having a contact angle to fluid greater than 90° as taught by Karwoski et al. such that it reduces thrombogenicity and reduces the likelihood of restenosis.

Claims 1,14 are rejected under 35 U.S.C. 103(a) as obvious over Oktay (2003/40791) in view of Karwoski et al. '907. Oktay shows (Fig. 10) a stent **1000** with

an array of microstructures **1050,1060** on a region of the surface of the stent. Oktay discloses (paragraph 69) the stent structure is made of metal. Oktay further illustrates (11A-11C) the stent includes electrically controllable structures **1040** for latching the edges of the tubular body. However, Oktay does not explicitly state the surface is hydrophobic with a contact angle greater than 90° when any drop of fluid contacts it. Karwoski et al. is explained as before. It would have been obvious to one of ordinary skill in the art to coat an inner surface to be hydrophobic with a contact angle to fluid greater than 90° as taught by Karwoski et al. with the stent of Oktay such that it is provided with a non-thrombogenic surface.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (WO 02/64019) in view of Karwoski et al. '907 as applied to claim 19 above, and further in view of Momma et al. (2005/27350). Bailey et al. as modified with Karwoski et al. is explained supra. However, Bailey et al. in view of Karwoski fail to disclose different substances to be released into the implantation site. Momma et al. teach that different medicinal substances can be utilized to deliver to the implantation site for different purposes, paragraphs 21,45. It would have been obvious to one of ordinary skill in the art to incorporate different drugs on the stent as taught by Momma et al. in the stent of Bailey et al. modified with Karwoski et al. such that it provides multiple therapeutic capabilities to encounter the biological responses of the body.

(10) Response to Argument

The amendment after final has not been entered as the amendment to claim 8 was found to have changed the scope of the claim. The current Appeal Brief is directed toward the assumption that amended claim 8 would be entered. As such, certain parts of the Brief are inconsistent with respect to the currently pending claims. For instance, the summary of claimed subject matter is directed toward claims 8 and 18 only.

It is also noted that claim 3 in the appendix of claims is incorrectly dependent from a claim 28 instead of claim 2.

A. First the Examiner would like to reiterate that claims 1-8,12,13,18-20 were rejected over Bailey in view of Karwoski. It is noted that Applicant did not discuss the references as applied against claims 1-7,12,13, thus it is the Examiner's contention that all limitations of claims 1-7, 12, and 13 are met by Bailey and Karwoski, and respectfully asks the Board to affirm this rejection. Applicant presents arguments for claim 8 only. Specifically Applicant argues that the rejection over Bailey in view of Karwoski fails to meet the claim limitations specifically for claim 8 and 18, in that the combined prior art allegedly did not disclose a drug delivery stent with at least one surface having an array of micro or nanostructures where the drug or pharmacological agent is located in the interstices of the array. The Examiner would like to refer the Applicant to recitations in Bailey that disclose a drug or pharmacological agent in the interstices of stent with micro structures, see page 4, lines 24,25, disclosing a stent. Bailey further discloses microstructures on the stent and includes pharmacological agents or drugs, page 5,

lines 2-11. Further Bailey discloses microgrooves or what can be considered interstitial spaces on the stent, page 10, lines 19,20. Bailey further discloses an energy source is applied to the stent to cause release or exposure of the drug or agent, page 23, lines 24-31. Bailey further teaches forms of energy that provide voltage, page 15, lines 17-19.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the control device affixed to the tubular member for varying hydrophobicity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The original version of claim 8, presented the control device was involved in the release of an agent or drug. This argument pertains to a different scope of the claim of which was not considered or entered. Applicant then argues Bailey does not describe a hydrophobic surface and is not inherent in the Bailey. The Examiner respectfully disagrees because metal clearly can be considered hydrophobic, but what Bailey did not describe was the claimed degree of hydrophobicity such that a drop of body fluid has a contact angle to the surface that is greater than 90 degrees. Karwoski was used for the teaching of providing the specific claimed surface hydrophobicity. Therefore the claims as presented are met by the combination because the hydrophobic surface as claimed is taught by Karwoski and the claims stated the control device pertained to releasing the drug, not varying the hydrophobicity. Applicants further argue that there was no indication that Bailey disclosed varying the penetration of interstices by body fluid. However, the Examiner

would like to refer Applicants to page 23, lines 21-31 stating the device being implanted has biological material which must be body fluid that carries binding agents that join with endothelial cell or smooth muscle cell precursors. Once this occurs cell regeneration can occur in the form of endothelialization.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Karwoski can be combined with Bailey despite Applicants stating Bailey disclosing a metal stent and thus the coating of Karwoski cannot be applied to such a stent. However, it is well known that different materials are capable of bonding together and for example Rathenow (20050079200) discloses that organic coatings can be applied with metal surfaces, see document.

B. Applicant failed to submit an argument pointing out disagreements with the examiner's contentions against the rejection of claims 1,2,5-7,9-11 as obvious over Momma et al. in view of Karwoski et al. Applicant only explained that since claim 8 was not rejected the claims avoid the references thus alleging the claim as amended should

be entered. However, Applicant has changed the scope of claim 8 and thus the Examiner's rejections are proper and should be affirmed.

C. Applicant failed to submit an argument pointing out disagreements with the examiner's contentions against the rejection of claims 1,2,5-7,15-17 as obvious over Shastri et al. in view of Karwoski et al. Applicant only explained that since claim 8 was not rejected the claims avoid the references thus alleging the claim as amended should be entered. However, Applicant has changed the scope of claim 8 and thus the Examiner's rejections are proper and should be affirmed.

D. Applicant failed to submit an argument pointing out disagreements with the examiner's contentions against the rejection of claims 1,14 as obvious over Oktay in view of Karwoski et al. Applicant only explained that since claim 8 was not rejected the claims avoid the references thus alleging the claim as amended should be entered. However, Applicant has changed the scope of claim 8 and thus the Examiner's rejections are proper and should be affirmed.

E. Applicants argue claim 21 is patentable over Bailey in view of Karwoski and Momma because claim 18 was argued above and its reasons. The Examiner presents the arguments above for claim 18 herein.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Brian E Pellegrino/

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